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Planning for Science ActivitiesQuality Implementing Procedure ID: OSTI-LLNL-QIP-2.2, Rev.0, Mod.0

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QA: QA

Planning for Science Activities

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1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the responsibilities and process for preparation, review, approval, revision/cancellation, and distribution of Technical Work Plans (TWPs) for activities subject to the OSTI-LLNL Quality Assurance Plan (QAP), Supplement III, which implements Supplement III of the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description (QARD),* DOE/RW-0333P. These activities include modeling, scientific investigation, laboratory and field testing, scientific and technical reports, and other science related documents. Plans for other activities may be completed in accordance with the requirements of this procedure, as directed by the Project Manager (PM).

2. SCOPE

This QIP applies to Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) personnel who prepare, revise, review, or approve plans for quality-related (Q) activities subject to Supplement III of the QAP or, if directed by the PM, non-Q (i.e., those activities determined not to be subject to QAP requirements) science activities for the OSTI-LLNL Project. This QIP is developed in accordance with OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Documents.*

This procedure does not apply to administrative and support activities that may be associated with the subject scientific activities if the administrative and support activities themselves are not covered by Supplement III of the QAP. Examples of such activities include:

- Infrastructure and support activities that are governed by other implementing procedures (e.g., document control, records management, procedure development, procurement, and configuration management)
- Program Management and Integration overhead accounts; management and oversight activities
- Human resource-related activities, such as personnel performance appraisals, personnel placement, and employee assistance
- Programmatic, cost estimating, and project control activities, such as financial, resource, program, cost, and schedule planning and monitoring (not including procurement of quality-related [Q] items or services, as described in the Memorandum & Guidance, which is subject to QAP requirements)
- Oral and written reports of work status (e.g., progress reports or presentations, not including reports required by the QAP)

- Administration activities, such as facilities/space management, motor pool operations, reprographics services, mail services, telecommunications, supplies, and recycle management.

For work activities performed by a subcontractor, the requirements for a TWP shall be identified in the procurement document scope of work, as applicable.

3. PROCEDURE

3.1 Preparing the TWP

3.1.1 The **PM** shall provide higher level planning (e.g., OCRWM Guidance and Funding Memorandum) to the Deputy PM for incorporation into OSTI-LLNL lower level planning documents.

3.1.2 The **PM/Deputy PM** (DPM) shall review the higher level planning and ensure TWP(s) are prepared for all activities subject to Supplement III. TWPs may control a single activity or multiple related activities.

3.1.3 The **PM/DPM** shall assign a TWP Originator (the **PM/DPM** may perform the responsibilities of the TWP Originator).

3.1.4 The **TWP Originator** shall obtain a Document Identifier (DI) number from the OSTI-LLNL Records Coordinator in accordance with OSTI-LLNL-QIP-6.0, *Document Control*. The DI number shall be placed on the cover sheet and on each page of the TWP.

3.1.5 For quality-related activities, the **TWP Originator** shall require the implementation of OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data.*

3.1.6 The **TWP Originator** shall prepare or revise the TWP using Attachment 1, which provides content requirements to be addressed.

A. If appropriate, assign the task of preparing portions of the draft TWP to Principal Investigators (PIs), model developers, or other scientific staff members to ensure all needed detail is included in the TWP. The TWP Originator is responsible for the integration and completeness of the TWP when multiple contributors assist in developing the TWP.

B. If applicable, the TWP shall include a discussion of model validation per Attachment 2, Levels of Model Importance, Validation, and Confidence.

C. Indicate changed portions of approved TWP(s) by placing black vertical lines in the margin on the page(s) where the changes were made. Change bars do not have to be used for complete revisions.

3.1.7 Once completed, the **TWP Originator** shall notify the **PM/DPM** for assignment of a LLNL Technical and QA Reviewer.

3.2 Reviewing the TWP

3.2.1 The **TWP Originator** shall prepare a review package for the draft TWP for OSTI-LLNL technical and QA reviews. Technical and QA reviews shall be conducted in accordance with OSTI-LLNL-QIP-6.1, *Document Review*. Individuals other than the originator shall perform the review. Reviewers shall be technically competent in the subject area of the document being reviewed. Review criteria to be used are documented in Attachment 3, Review Criteria for Technical Work Plans. Review criteria shall, as a minimum, consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.

3.2.2 Upon completion of the technical and QA reviews, prepare a review package for external organizations (if multiple organizations are involved).

A. The TWP Originator shall provide a memorandum to the reviewing organizations, containing review criteria, documentation for the review, instructions for completing the documentation, and a due date.

B. Reviewing organizations shall be identified on the Review Record (OSTI-LLNL-QIP-6.1, Attachment 2).

3.2.3 The **TWP Originator** shall:

A. Document responses to all technical comments, including rationale for not including or partially including technical comments.

B. Modify the review draft of the TWP to reflect resolution of technical comments to be addressed.

C. Obtain reviewers' acceptance of technical comment responses.

D. Elevate any unresolved technical comments to the next level(s) of management of the TWP Originator and reviewers until resolution is achieved. The resolution shall be documented on the Comment Sheet, Review Copy mark-up, or electronically.

E. Forward the modified concurrence draft TWP to the Deputy PM.

3.2.4 The **PM/DPM** shall ensure the resolution of comments has not adversely affected the TWP. Resolve any adverse impacts with the TWP Originator and the reviewers, and return the modified concurrence draft TWP, with any changes, to the TWP Originator.

3.3 Approving the TWP

3.3.1 The **TWP Originator** shall prepare the final TWP, establish the effective date, and sign and date the TWP as the originator. Obtain the signature and date of the **PM/DPM** indicating approval. Obtain the final approval signature and date

of the PM. Submit the approved TWP to the Records Coordinator for issuance as a controlled document per OSTI-LLNL-QIP-6.0.

3.3.2 Approved "Q" TWPs shall be submitted to OCRWM/OSTI for acceptance prior to commencing work subject to the QARD. Work designated as "non-Q" may begin prior to OCRWM OSTI acceptance of the TWP. If OCRWM/OSTI comments require changes to the TWP, changes shall be incorporated by revision or modification per Section 3.4, below.

3.4 Revising or Canceling TWP(s)

3.4.1 The **PM/DPM** shall review any proposed changes to determine if there is a change to Guidance and Funding Memorandum and/or a need to revise or modify the TWP(s). Minor changes (i.e., no significant changes in work scope, conceptual approach, or validation needs/criteria) do not require a revision or modification to the TWP.

3.4.2 Revise or modify the TWP(s) in accordance with Sections 3.1 through 3.3, as applicable.

A. Modifications are changes that affect a limited section of the document. No more than three modifications shall be issued against a TWP revision.

B. Revisions are required following issuance of a third modification to the document, or sooner if the changes to the document are substantial.

3.4.3 If the work scope has been completed, cancel the TWP in accordance with OSTI-LLNL-QIP-6.0.

3.4.4 If the revised TWP supersedes or replaces a controlled planning document, decontrol the superseded planning document in accordance with OSTI-LLNL-QIP-6.0.

3.5 Distributing TWP(s)

3.5.1 Upon completion, revision, or cancellation of TWP(s), the **Records Coordinator** shall issue or cancel the TWP in accordance with OSTI-LLNL-QIP-6.0, and submit associated records to the Records Center (RC) in accordance with Section 4.0

4. RECORDS

The records listed below shall be collected and submitted to the RC in accordance with OSTI-LLNL-QIP-17.0, *Records Management,* as individual records or included in a records package, as specified.

4.1 QA Records

Records Package for QA TWPs:

Review copy of the TWP;
Review Record(s) and Comment Sheet(s) and/or records of reviews conducted by electronic mail, as appropriate, objective evidence of comment resolution, and objective evidence of reviewers' concurrence; and
Final approved TWP.

4.2 Non-QA Long-Term Records

Records Package for non-QA TWPs:

Review copy of the TWP;
Review Record(s) and Comment Sheet(s) and/or records of reviews conducted by electronic mail, as appropriate, objective evidence of mandatory comment resolution, and objective evidence of reviewers' concurrence;
Final approved TWP.

4.3 Non-QA Short-Term Records (three years or less retention)

None

5. RESPONSIBILITIES

5.1 The **PM** is responsible for providing higher-level planning to the DPM, resolving disputes elevated during review resolution, and approving the TWP.

5.2 The **PM/DPM** is responsible for ensuring that TWP(s) are prepared for all QA activities subject to Supplement III, for assigning a TWP Originator, assigning technical and QA reviewers per OSTI-LLNL-QIP-6.1, and for reviewing and approving the TWP.

5.3 The **TWP Originator** is responsible for evaluating activities per OSTI-LLNL-QIP-SV.0, and for the preparation and revision (or delegation thereof) of the applicable TWP(s).

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

DI	Document Identifier
DOE	U.S. Department Of Energy
DPM	Deputy Project Manager PI Principal Investigator
PM	Project Manager
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
Q	Quality-related
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
TWP	Technical Work Plan

YMP Yucca Mountain Project

6.2 Definitions

Activity: An organized or supervised action performed to complete a specific task or function (e.g., modeling, scientific analyses, scientific testing, or preparation of documents/products).

Field Testing: Any testing activity that requires site preparation (e.g., excavation and surface or subsurface drilling), instrumentation, and subsequent observation or measurement to collect data or information to support project work activities

Higher Level Planning: OCRWM Documents that identify the requirements and overall work scope that is to be passed on to sub-organizations tasked with implementing the work scope (e.g., Guidance and Funding Memorandum).

Laboratory Testing: A non-field testing activity that uses laboratory methods, techniques, and equipment to collect data or information to support project work activities.

Lower Level Planning: Documents (e.g., TWP, scientific notebooks) that provide specific details needed to perform a portion of the larger work scope identified in higher level planning.

Scientific Investigation: Any observation, identification, description, experimental study, or analysis and explanation of natural phenomena (QARD).

Technical Work Plan (TWP): A lower level planning document for an activity, or a logical grouping of related activities described and controlled by higher level planning.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-6.0, *Document Control*

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SI.0, *Software Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

OSTI-LLNL-QIP-SIII.1, *Technical Reports*

OSTI-LLNL-QIP-SIII.2, *Model Reports*

OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data*

8. ATTACHMENTS

Attachment 1 - Technical Work Plan Content

Attachment 2 - Levels of Model Importance, Validation, and Confidence

Attachment 3 - Review Criteria for Technical Work Plans

9. REVISION HISTORY

2/25/05 Revision 0/Modification 0

Initial Issue

10. APPROVALS

Preparer: L. Gouveia / Leigh Gouveia — Date: 2/25/05

Technical Reviewer: Qinhong Hu / QINHONG HU — Date: 2/25/05

QA Reviewer: Victor J. Barish Jr / VICTOR J. BARISH JR — Date: 2/25/05

Project Manager: David B. McCallen / DAVID B. McCALLEN — Date: 2/25/05

TECHNICAL WORK PLAN CONTENT

CHANGE HISTORY

Use numerals to indicate the revision/modification number. If the TWP is a new document, state "Initial issue" on the Change History page. If changes to the TWP are extensive, state "Complete revision" on the Change History page, and briefly summarize the changes. Use revisions/modifications to address changes in previously documented work scope. Provide DI number and title of TWP(s) superseded by the revision.

CONTENT

Ensure that each item is addressed for each major activity. If any items do not apply to the activity, state N/A and provide an explanation as to why they do not apply.

1. WORK SCOPE

Describe the scope of work:

- State the overall technical and/or performance objectives or requirements to be met by completion of the work. TWPs may control a single activity or multiple related activities.
- List all major activities (primary tasks) and products (e.g., data qualification, modeling, scientific analyses, scientific testing).
- Address provisions for determining the accuracy, precision, and representativeness of results.

2. SCIENTIFIC APPROACH OR TECHNICAL METHODS

2.1 FOR ALL WORK ACTIVITIES:

- State the intended use and/or purpose of each activity and/or product. Identify any tests, test requirements, and instructions for performing the test, as applicable. Identify users/customers of the outcomes from the activity.
- Describe the scientific approach and technical methods for each activity.
- Identify methods for data collection, data reduction, and recording results.
- Address provisions for handling unexpected test results, unanticipated test conditions, or occurrence of off-normal events during testing.

2.1.1 Additional steps for modeling activities (see Attachment 2, Levels of Model Importance, Validation, and Confidence):

- Model validation criteria shall be explicitly specified for ensuring the appropriate level of confidence has been obtained, as required by OSTI-LLNL-QIP-SIII.2, *Model Reports*.

- Identify the level of confidence/validation required for each model, as required by OSTI-LLNL-QIP-SIII.2.

- Identify and provide justification for the model validation activity/activities to be completed after the model has been developed, dependent upon and consistent with the model's intended use and required level of confidence, including one or more of the following:

  - Corroboration of model results with data acquired from the laboratory, field experiments, analog studies, or other relevant observations, not previously used to develop or calibrate the model.

  - Corroboration of results with alternative mathematical models.

  - Corroboration with information published in refereed journals or literature.

  - Peer review (if used, an OSTI-LLNL-QIP will be developed to control the activity prior to performing the work).

  - Technical review by reviewers independent of the development, checking, and review of the model documentation (the Originator, Checker, and reviewers assigned to the model document/activity may not serve as independent post-development model validation technical reviewers).

  - Corroboration of abstraction or system model results to the results of the validated mathematical model(s) from which the abstraction or system model was derived, including corroboration with results of auxiliary analyses used to provide additional confidence in system model results.

  - Corroboration of pre-test model predictions to data collected during subsequent, associated testing.

3. INDUSTRY STANDARDS, FEDERAL REGULATIONS, DOE ORDERS, REQUIREMENTS, AND ACCEPTANCE/COMPLETION CRITERIA

- State directly applicable standards, including industrial (e.g., American Society for Testing and Materials Standards) and/or technical standards.

- State any sections or subsections of the Code of Federal Regulations, DOE orders, and/or regulatory requirements for additional information that needs to be directly addressed by the OSTI-LLNL activities or product(s), but are not identified by the Guidance and Funding Memorandum or procedure interfaces, if any.

- State the provisions for determining the level of accuracy, precision, and representativeness of results of each activity.

- State applicable acceptance and/or completion criteria identified in higher level planning for each activity and product, including DOE acceptance criteria and contractor completion criteria.

4. IMPLEMENTING DOCUMENTS

- Identify the specific implementing procedures that will be required to directly conduct each activity (e.g., OSTI-LLNL-QIP-SIII.0, OSTI-LLNL-QIP-5.0, and OSTI-LLNL-QIP-SIII.1, OSTI-LLNL-QIP-SIII.2, etc.).

- For non-Q activities (as determined in Section 8 of this outline), state the specific procedural requirements that will be applicable to directly conduct each activity (e.g., requirements from OSTI-LLNL-QIP-SIII.0).

5. EQUIPMENT

- Identify the major field or laboratory systems or equipment necessary to conduct the work.

- Identify calibration requirements and methods for addressing instrument error. Measuring and test equipment calibration shall be documented in accordance with OSTI-LLNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards.*

6. RECORDS

Provide instructions to users of the TWP to collect and submit all required records generated as a result of implementing procedures and the documentation of objective evidence of the results of the work performed to the OSTI-LLNL Records Coordinator for submittal to the RC, in accordance with OSTI-LLNL-QIP-17.0, *Records Management.*

7. QUALITY VERIFICATIONS

Identify any quality verifications, other than audits (i.e., mandatory hold points and readiness reviews), that are required during the execution of the TWP.

8. PREREQUISITES, SPECIAL CONTROLS, ENVIRONMENTAL CONDITIONS, PROCESSES, OR SKILLS

- Determine whether each activity is subject to the requirements of the QARD. Provide justification for any activity determined to be not subject to the QARD. The following activities are subject to the QARD.

- Sample collection and the collection and analysis of data to support performance assessment.

- Activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

- Activities related to the high-level waste from development through qualification, production, and acceptance.

- Describe any prerequisites that must be satisfied before work begins, including calibration of measuring and test equipment, and receipt of data/input(s) under development. Identify the organizations responsible for developing the input(s).

- If the activity meets the criteria of OSTI-LLNL-QIP-SV.0, list any additional method(s) or implementing documents to be used for control of electronic management of information.

- State whether any special environmental controls are required to conduct the activity. For scientific testing, identify any special environmental conditions (e.g., non-ambient conditions), special construction requirements (e.g., bed/apparatus configuration), or other requirements or controls.

- Identify any special training/qualification requirements for personnel performing the work activity.

9. SOFTWARE

- List software to be used to conduct the work. List the associated software tracking numbers, if known.

- Indicate whether the listed software is qualified or unqualified.

10. ORGANIZATIONAL INTERFACES

Identify any organizational interfaces, including input and customer organizations and state their roles/responsibilities.

11. PROCUREMENT

Provide a description of the procurement processes pertinent to the activity, if known. If not known, identify, as a minimum, expected types of subcontract services to be procured (e.g., analytical services, calibration services), indicate competitive versus sole source, and the estimated schedule and duration of these subcontracts.

12. REFERENCES

List references as applicable, excluding those listed as implementing documents in Section 4.

LEVELS OF MODEL IMPORTANCE, VALIDATION, AND CONFIDENCE

This attachment describes the levels of model importance and corresponding validation guidelines commensurate with each level of model importance. OSTI-LLNL-QIP-SIII.2 requires that model components be validated for their intended purpose and stated limitations, and to the level of confidence required by the component's relative importance to the potential performance of the repository system. The level of validation increases with an increasing level of model importance ranging from low to moderate to high. OSTI-LLNL models fall under low to moderate levels, defined as follows:

Level I Validation

Level I validation shall include, at a minimum, discussion of documented decisions and activities that are implemented during the model development process that build confidence and verify that a reasonable, credible, technical approach using scientific and engineering principles was taken to:

a) Evaluate and select input parameters and/or data.

b) Formulate defensible assumptions and simplifications.

c) Ensure consistency with physical principles, such as conservation of mass, energy, and momentum.

d) Represent important future state (aleatoric), parameter, and alternative model uncertainties.

e) Ensure simulation conditions have been set up to span the range of intended use and avoid inconsistent outputs.

f) Ensure that model predictions (performance parameters) adequately represent the range of possible outcomes, consistent with important uncertainties.

For post-model development validation, choose a single method described in OSTI-LLNL-QIP-SIII.2, consistent with a model of limited importance to the mean annual dose.

LEVEL II VALIDATION

Level II validation shall include Level I criteria a) through f) and a single post-development model validation method described in OSTI-LLNL-QIP-SIII.2, consistent with a model of moderate importance to mean annual dose. Document rationale for selection of post model development activities as described in Attachment 1.

Table 1 summarizes levels of model validation for examples of the component models developed historically by LLNL for the Yucca Mountain Project (YMP).

Table 1. Examples of Minimum Levels of Model Validation as used in YMP

Model Validation Area	TSPA Component Model	Level of Validation
Climate and Infiltration	Climate and Infiltration	I
Unsaturated Zone Flow	Unsaturated Zone Flow	I
Seepage into Emplacement Drifts	Seepage into Emplacement Drifts	I
In-Drift Moisture and Chemistry	Invert Moisture and Chemistry	I
	Waste Package/Drip Shield Moisture and Chemistry	II
Radionuclide Release Rates and Concentrations	Radionuclide Inventory	II
	Radionuclide Screening	I
	Drift Shadow	I
Unsaturated Zone Radionuclide Transport	Unsaturated Zone Radionuclide Transport	II

REVIEW CRITERIA FOR TECHNICAL WORK PLANS

TWP STANDARD REVIEW CRITERIA

1. Does the Document Identifier (DI) appear on each page of the TWP?

2. Is each section addressed, as listed in Attachment 2, Technical Work Plan Content? If not applicable, does the Originator provide justification for the non-applicability within the section?

3. Does the TWP cover all applicable activities subject to Supplement III, *Scientific Investigation,* per the upper level planning documents?

4. Are the responsibilities clearly delineated and in accordance with established organization division of responsibility?

5. Is the purpose and scope clearly specified?

6. Have the evaluation results per OSTI-LLNL-QIP-SV.0, *Management of OSTI-LLNL Electronic Data,* been documented in Section 8 of the TWP?

TWP QUALITY ASSURANCE REVIEW CRITERIA

1. Are specific responsibilities and authorities consistent with the OCRWM Guidance and Funding Memorandum or other applicable requirements?

2. Is the activity to which the TWP applies clearly identified?

3. Is the TWP appropriately integrated with other procedures or processes?

4. Does the TWP adequately address applicable requirements?

5. Does the TWP include or reference appropriate acceptance criteria for determining those prescribed processes have been satisfactorily accomplished?

TWP TECHNICAL REVIEW CRITERIA

1. Is the TWP technically adequate, correct, complete, accurate, applicable to the issue being addressed?

2. If applicable, are potential interactions with other technical work or outside organizations addressed adequately?

3. Has the needed level of confidence been identified for each model covered in the TWP, and is the level of confidence appropriate for the intended use of the model(s).

4. Are model validation plans adequate and appropriate to obtain the level of confidence required by the model's relative importance to the potential performance of the repository system?

5. Are validation criteria identified for modeling activities, and are the criteria appropriate for the intended use and for the level of confidence to be obtained for the model(s)?